

110TH CONGRESS
1ST SESSION

S. 2404

To amend title XVIII of the Social Security Act to improve payments under the Medicare clinical laboratory fee schedule.

IN THE SENATE OF THE UNITED STATES

DECEMBER 3, 2007

Mr. SCHUMER introduced the following bill; which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to improve payments under the Medicare clinical laboratory fee schedule.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE AND TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Medicare Advanced Laboratory Diagnostics Act of
6 2007”.

7 (b) **TABLE OF CONTENTS.**—The table of contents of
8 this Act is as follows:

Sec. 1. Short title and table of contents.

TITLE I—DEMONSTRATION PROJECT FOR NEW PAYMENT RATE-
SETTING PROCESS

Sec. 101. Establishment of Medicare demonstration project to evaluate new approaches to coding and payment for certain molecular diagnostic tests.

TITLE II—CHANGES TO THE MEDICARE CLINICAL LABORATORY FEE SCHEDULE

Sec. 201. Fee schedule and national limitation amounts for clinical diagnostic laboratory tests.

Sec. 202. Issuance of regulations on gap-filling for Medicare fee schedule for clinical diagnostic laboratory tests.

Sec. 203. Increased transparency of process for determining fee schedule amounts for new tests.

Sec. 204. Advance notice of clinical diagnostic laboratory test amounts being considered for adjustment under inherent reasonableness authority.

1 **TITLE I—DEMONSTRATION** 2 **PROJECT FOR NEW PAYMENT** 3 **RATE-SETTING PROCESS**

4 **SEC. 101. ESTABLISHMENT OF MEDICARE DEMONSTRATION** 5 **PROJECT TO EVALUATE NEW APPROACHES** 6 **TO CODING AND PAYMENT FOR CERTAIN MO-** 7 **LECULAR DIAGNOSTIC TESTS.**

8 (a) ESTABLISHMENT OF DEMONSTRATION.—

9 (1) DEMONSTRATION OF NEW APPROACHES TO
10 CODING AND PAYMENT.—The Secretary of Health
11 and Human Services (in this section referred to as
12 the “Secretary”) shall establish a demonstration
13 project under this section (in this section referred to
14 as the “demonstration”) to evaluate new approaches
15 to coding and payment under the Medicare program
16 for clinical diagnostic laboratory tests included in
17 the demonstration (in this section referred to as “in-
18 cluded tests”).

1 (2) DURATION.—The demonstration and any
2 payment amounts assigned under the demonstration
3 shall apply solely to claims submitted for included
4 tests during the 12-calendar-quarter period that be-
5 gins with the first day of the first calendar quarter
6 to begin at least 250 days after the date of the en-
7 actment of this Act.

8 (3) SCOPE.—The demonstration shall apply on
9 a national basis to included tests in all settings for
10 which payment for such tests would (but for the
11 demonstration) be made under the fee schedules and
12 limitation amounts established under section
13 1833(h) of the Social Security Act (42 U.S.C.
14 1395l(h)).

15 (4) ISSUANCE OF TEMPORARY HCPCS CODES;
16 CONTINUED APPLICATION OF SUCH CODES.—The
17 Secretary shall issue a temporary code or codes
18 under the Health Care Procedure Coding System
19 (HCPCS) when needed for an included test, and
20 such code or codes—

21 (A) shall continue to apply to the test until
22 a permanent code or codes is assigned; and

23 (B) shall not cease to apply solely because
24 the demonstration ends.

25 (b) INCLUDED TESTS.—

1 (1) ELIGIBLE TESTS.—A clinical diagnostic lab-
2 oratory test is eligible to be an included test under
3 the demonstration if—

4 (A) the test is a new or existing molecular
5 diagnostic test that (but for its inclusion in the
6 demonstration) could be paid under the fee
7 schedules and national limitation amount estab-
8 lished under section 1833(h) of the Social Secu-
9 rity Act (42 U.S.C. 1395l(h)) for the test; and

10 (B) there is the prospect—

11 (i) for wide usage of the test in mul-
12 tiple geographic areas; and

13 (ii) that development of a new code,
14 or payment, or both, for the test under the
15 demonstration will result in reduced ad-
16 ministrative complexity and improved effi-
17 ciency.

18 (2) INCLUDED TESTS.—A clinical diagnostic
19 laboratory test shall be treated as an included test
20 if—

21 (A) an interested party submits a request
22 to the standing panel established under sub-
23 section (c) that the test be included in the dem-
24 onstration; and

1 (B) the standing panel determines that the
 2 test is an eligible test under paragraph (1).

3 (3) DEFINITIONS.—For purposes of this sec-
 4 tion—

5 (A) the term “molecular diagnostic test”
 6 means a clinical diagnostic laboratory test per-
 7 formed on deoxyribonucleic (DNA), ribonucleic
 8 acid (RNA), or protein that is drawn from a
 9 human being or from a disease-causing orga-
 10 nism for genomic or proteomic analysis; and

11 (B) the term “interested party” means,
 12 with respect to a request for inclusion of molec-
 13 ular diagnostic test in the demonstration, an in-
 14 dividual entitled to benefits under title XVIII of
 15 the Social Security Act, a manufacturer of the
 16 test, a clinical laboratory offering the test, a
 17 professional society, the Centers for Medicare &
 18 Medicaid Services, a private payer for such test,
 19 and a physician or other health care practi-
 20 tioner.

21 (c) STANDING PANEL.—

22 (1) APPOINTMENT.—Not later than 60 days
 23 after the date of the enactment of this section, the
 24 Secretary shall appoint a standing panel (in this sec-
 25 tion referred to as the “standing panel” or “panel”)

1 to determine whether a test is an included test and
2 make recommendations to the Secretary on the ap-
3 propriate coding of, and payment for, designated
4 clinical diagnostic laboratory tests under the dem-
5 onstration.

6 (2) COMPOSITION OF PANEL.—

7 (A) IN GENERAL.—The standing panel
8 shall be comprised of 12 members. Two of such
9 members shall be non-voting representatives of
10 the Administrator of the Centers for Medicare
11 & Medicaid Services. The Secretary shall ap-
12 point the other 10 members from—

13 (i) organizations representing large
14 clinical laboratories;

15 (ii) organizations representing small
16 clinical laboratories;

17 (iii) organizations representing physi-
18 cians with expertise in clinical diagnostic
19 laboratory tests;

20 (iv) organizations representing non-
21 physician laboratorians with expertise in
22 such tests;

23 (v) organizations representing manu-
24 facturers of such tests;

1 (vi) organizations representing indi-
 2 viduals entitled to benefits under title
 3 XVIII of the Social Security Act;

4 (vii) organizations representing pri-
 5 vate payers for such tests (but not more
 6 than one member may be appointed to rep-
 7 resent such organizations);

8 (viii) individuals with expertise in
 9 measuring resource utilization by clinical
 10 laboratories in performing tests; and

11 (ix) individuals with other relevant ex-
 12 pertise.

13 (B) TERMS OF OFFICE.—Each member of
 14 the panel shall be appointed for the life of the
 15 panel, except that any individual appointed to
 16 fill a vacancy shall be appointed for the remain-
 17 der of the term of the individual who is being
 18 replaced. Any vacancy shall be filled in the
 19 same manner, and with a representative of the
 20 same category under subparagraph (A), as the
 21 individual being replaced.

22 (3) RULES GOVERNING PANEL.—

23 (A) IN GENERAL.—The panel shall elect its
 24 chair. A quorum shall be required to conduct

1 the business of the panel, and eight members of
2 the panel shall constitute a quorum.

3 (B) COMPENSATION.—While serving on
4 the business of the panel (including travel
5 time), a member of the panel shall be entitled
6 to compensation at the per diem equivalent rate
7 provided for level IV of the Executive Schedule
8 under section 5315 of title 5, United States
9 Code, and while so serving away from home and
10 the member's regular place of business, a mem-
11 ber may be allowed travel expenses as author-
12 ized by the chair of the panel.

13 (C) STAFFING.—

14 (i) DETAILING.—The panel may seek
15 such assistance and support of its duties
16 from appropriate Federal departments and
17 agencies.

18 (ii) OUTSIDE EXPERTS.—The panel
19 may retain the services of such outside ex-
20 perts as are necessary for the evaluation of
21 a request under this section, and such ex-
22 perts shall not be voting members of the
23 panel.

24 (D) MEETINGS.—The panel shall meet at
25 the call of the chair and at such intervals

(which shall not be less than quarterly) as may be necessary for the conduct of its business. The agenda of each meeting and a notice of its date shall be published at least 30 days before the date the meeting occurs, and, except as provided in subparagraph (E), meetings of the panel shall be open to the public.

(E) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the panel, but the panel may close any portion of a meeting that could be closed if such Act applied.

(F) TERMINATION OF PANEL.—The panel shall terminate not more than 180 days after the close of the demonstration.

(d) FORM AND CONTENT OF REQUESTS FOR INCLUSION IN THE DEMONSTRATION.—A request for inclusion of a clinical diagnostic laboratory test in the demonstration shall be submitted in such form, and shall contain such information as the standing panel may require, including at least—

(1) any coding and payment determinations requested with respect to the test; and

(2) any documentation in support of—

1 (A) the eligibility of the test for inclusion
2 in the demonstration; and

3 (B) any coding and payment determina-
4 tions requested with respect to the test, includ-
5 ing data on the typical resources necessary to
6 perform the test.

7 The Secretary shall cause to have published in the
8 Federal Register and on an appropriate Internet site
9 public notice of each such request. Such information
10 shall be supplied to the Secretary by the standing
11 panel.

12 (e) CRITERIA FOR EVALUATING REQUESTS FOR DE-
13 TERMINATIONS IN CODING AND PAYMENT.—

14 (1) IN GENERAL.—In determining whether a
15 requested payment determination should be granted,
16 and what the new payment amount for a test should
17 be, the standing panel (in making its recommenda-
18 tions to the Secretary) and the Secretary (in deter-
19 mining whether to grant such a determination) shall
20 take into account typical resources necessary to per-
21 form the test, the expected impact of the test on,
22 and value of the test to, patient care management,
23 and such other factors as the standing panel and the
24 Secretary, respectively, determine to be relevant to
25 the determination.

1 (2) STANDING PANEL.—Not later than 180
2 days after the appointment of all of the members of
3 the panel, the panel shall, after consultation with the
4 Secretary, establish and make available to the pub-
5 lic—

6 (A) standards and parameters for deter-
7 mining whether to recommend to the Secretary
8 a coding or payment determination specified in
9 a request for inclusion of a test in the dem-
10 onstration, which shall include a listing of data
11 elements necessary to support a request and a
12 standardized procedure for collecting and sub-
13 mitting data to the panel on typical resources
14 necessary to perform a test;

15 (B) policies and procedures for protecting
16 the confidentiality of financial and other propri-
17 etary data submitted to the panel in support of
18 a request; and

19 (C) resource intervals or resource bands
20 (as described in subsection (g)(1)) that the
21 panel recommends that the Secretary should
22 use for the assignment of included tests under
23 the demonstration.

24 (3) SECRETARIAL DETERMINATIONS.—The Sec-
25 retary shall develop and make available to public on

1 an Internet site guidance documents on the stand-
2 ards and parameters that will be applied in making
3 Secretarial determinations and on the resource inter-
4 vals or resource bands to be used under the dem-
5 onstration and on whether to grant a request for a
6 payment or coding determination. Such guidance
7 documents shall be developed, which shall be made
8 available to the public at least 10 days before the be-
9 ginning of the demonstration, in a manner similar to
10 the manner in which guidance documents are devel-
11 oped under section 701(h) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 371(h)).

13 (4) AUTHORITY TO RECOMMEND REVISIONS TO,
14 AND TO REVISE, RESOURCE INTERVALS OR RE-
15 SOURCE BANDS.—Nothing in this section shall be
16 construed as limiting the authority of the standing
17 panel to recommend, or the Secretary to adopt, new
18 resource intervals or resource bands to accommodate
19 changes in technology.

20 (f) REVIEW PROCESS.—

21 (1) REQUESTS FOR INCLUSION IN DEMONSTRA-
22 TION.—An interested party may submit a request
23 for inclusion of a test in the demonstration to the
24 standing panel at any time during a calendar year
25 for which the demonstration is in effect, except that

1 the standing panel may decline to review and make
2 recommendations or determinations with respect to
3 any request that would result in a requested coding
4 or payment determination being effective for a pe-
5 riod of less than 4 calendar quarters.

6 (2) RECOMMENDATIONS OF STANDING
7 PANEL.—The standing panel shall review each re-
8 quest for a coding or payment determination that is
9 made with respect to an included test. Applying the
10 standards and parameters developed under sub-
11 section (e)(2)(A), the panel shall make a rec-
12 ommendation to the Secretary with respect to each
13 requested determination.

14 (3) SECRETARIAL DETERMINATIONS.—

15 (A) QUARTERLY DETERMINATIONS.—The
16 Secretary shall make determinations on whether
17 to grant requested coding and payment deter-
18 minations on a quarterly basis, but is not re-
19 quired to make such a determination for every
20 request made (or with respect to which a rec-
21 ommendation is received from the standing
22 panel) during a particular quarter.

23 (B) TIME FRAMES FOR DETERMINA-
24 TIONS.—Determinations of the Secretary shall
25 be made in a timely manner in accordance with

1 time frames developed by the standing panel
2 taking into account factors such as when a re-
3 quest (and a recommendation with respect to
4 the request) is made during a quarter, the par-
5 ticular type of test involved, and the staffing
6 and resources that may be required to review
7 the request.

8 (g) PAYMENT METHODOLOGY.—

9 (1) IN GENERAL.—Included tests shall be paid
10 in accordance with a methodology, developed by the
11 standing panel, that establishes resource intervals or
12 resource bands in a manner similar to those that are
13 used as new technology ambulatory payment classi-
14 fication groups for hospital outpatient services under
15 section 1833(t) of the Social Security Act (42
16 U.S.C. 1395l(t)), with a test being assigned to the
17 interval or band that most closely approximates the
18 typical resources necessary for a laboratory to per-
19 form the test. Tests that are included tests for pur-
20 poses of this section shall be excluded from any dem-
21 onstration project under section 1847(e) of such Act
22 (42 U.S.C. 1395w-3(e)).

23 (2) PANEL RECOMMENDATIONS; SECRETARIAL
24 DETERMINATIONS.—

1 (A) RECOMMENDATIONS; SECRETARIAL
2 DETERMINATIONS.—The standing panel shall
3 recommend to the Secretary a resource interval
4 or resource band to which an included test
5 should be assigned, and the Secretary may as-
6 sign such test to such band or interval or to an-
7 other band or interval the Secretary determines
8 to more closely approximate the typical re-
9 sources necessary to perform the test.

10 (B) EXPLANATION OF DETERMINATION
11 THAT DIFFERS FROM RECOMMENDATION.—If
12 the Secretary assigns a test to an interval or
13 band other than that recommended by the
14 standing panel, the Secretary shall provide a
15 detailed written explanation of the reasons for
16 determining that such other interval or band is
17 more appropriate.

18 (3) EFFECTIVE DATE OF SECRETARIAL DETER-
19 MINATION.—A determination by the Secretary with
20 respect to a coding or payment determination for an
21 included test shall become effective as of the first
22 day of the calendar quarter following the calendar
23 quarter in which the determination is made.

24 (4) PERIODIC LOOK-BACKS OF INTERVAL OR
25 BAND ASSIGNMENTS.—At the request of the inter-

1 ested party that submitted the initial request for a
2 test to be included in the demonstration or of a
3 member of the standing panel, the standing panel
4 may review the appropriateness of the payment in-
5 terval or band to which the test is assigned and
6 make a recommendation to the Secretary that the
7 assignment be changed. The Secretary may accept
8 or reject such recommendation, and if the rec-
9 ommendation is rejected, the Secretary shall provide
10 a detailed explanation of the reasons for such rejec-
11 tion.

12 (5) PUBLICATION OF DETERMINATIONS.—The
13 Secretary shall publish determinations under this
14 subsection in a timely manner on an appropriate
15 Internet site.

16 (h) REPORTS TO CONGRESS.—

17 (1) IN GENERAL.—The Secretary shall submit
18 interim and final reports on the demonstration to
19 the Committees on Ways and Means and Energy
20 and Commerce of the House of Representatives and
21 the Committee on Finance of the Senate. The in-
22 terim report shall be submitted not later than the
23 close of the second year of the demonstration, and
24 the final report shall be submitted not later than
25 180 days after the close of the demonstration.

1 (2) CONTENT OF REPORTS.—The reports sub-
2 mitted under paragraph (1) shall include interim
3 and final—

4 (A) determinations on whether coding and
5 payment assignments under the demonstration
6 provide for—

7 (i) more equitable and accurate pay-
8 ment for included tests; and

9 (ii) reduced administrative complexity,
10 improved efficiency, and improved access
11 to care; and

12 (B) recommendations on—

13 (i) whether the alternative mechanism
14 for determining payment and coding for in-
15 cluded tests should be continued for such
16 tests beyond the 12-calendar-quarter pe-
17 riod the demonstration is in effect; and

18 (ii) whether the application of such
19 mechanism should be expanded to include
20 other new clinical diagnostic laboratory
21 tests for which payment would otherwise
22 be made under the fee schedules and limits
23 established under section 1833(h) of the
24 Social Security Act (42 U.S.C. 1395l(h)).

1 (3) COMMENTS BY STANDING PANEL.—The
 2 standing panel shall submit comments to the com-
 3 mittees referred to in paragraph (1) on the interim
 4 and final reports of the Secretary.

5 (i) AUTHORIZATION OF APPROPRIATIONS.—There
 6 are authorized to be appropriated for each of fiscal years
 7 2008 through 2013, such sums as may be necessary to
 8 carry out this section.

9 **TITLE II—CHANGES TO THE**
 10 **MEDICARE CLINICAL LAB-**
 11 **ORATORY FEE SCHEDULE**

12 **SEC. 201. FEE SCHEDULE AND NATIONAL LIMITATION**
 13 **AMOUNTS FOR CLINICAL DIAGNOSTIC LAB-**
 14 **ORATORY TESTS.**

15 (a) IN GENERAL.—Section 1833(h) of the Social Se-
 16 curity Act (42 U.S.C. 1395l(h)) is amended by adding at
 17 the end the following new paragraph:

18 “(9)(A) For purposes of this paragraph:

19 “(i) The term ‘an amount determined under
 20 this subsection’ means, with respect to a clinical lab-
 21 oratory test, the fee schedule amount determined
 22 under paragraph (2)(A)(i) for the test or the limita-
 23 tion amount determined under paragraph (4)(B) for
 24 the test.

1 “(ii) The terms ‘appropriate medicare adminis-
2 trative contractor’ and ‘medicare administrative con-
3 tractor’ have the meaning given to such terms under
4 section 1874A(a)(3).

5 “(iii) The term ‘erroneous decision’ means, with
6 respect to the determination of an amount deter-
7 mined under this subsection, any decision, calcula-
8 tion, judgment or other action by the Secretary or
9 a medicare administrative contractor that, based
10 upon consideration of currently known facts, needs
11 to be modified to produce a fair and equitable pay-
12 ment amount, except that such term does not in-
13 clude typographical or clerical errors.

14 “(iv) The term ‘non-governmental party’ in-
15 cludes—

16 “(I) a provider of services (as defined in
17 section 1861(u)) that furnishes clinical diag-
18 nostic laboratory tests for which payment may
19 be made under this subsection;

20 “(II) a supplier (as defined in section
21 1861(d)) that furnishes such tests; and

22 “(III) a manufacturer of a test or of any
23 supplies or equipment that are used in per-
24 forming such test.

1 “(B) An amount determined under this subsection
2 may be changed solely on the basis of—

3 “(i) in the case of a change other than a change
4 to correct an erroneous decision in determining such
5 amount, the authority provided by the preceding
6 provisions of this subsection, section 1842(b)(8), or
7 any regulations, manual instructions, or other regu-
8 latory guidance implementing such provisions; or

9 “(ii) in the case of a change to correct an erro-
10 neous decision in determining such an amount, the
11 authority provided by subparagraphs (C), (D), and
12 (E).

13 “(C) Any erroneous decision in determining an
14 amount under this subsection may be corrected only if—

15 “(i) a non-governmental party submits a re-
16 quest under subparagraph (D) or (E) for correction
17 of the erroneous decision; and

18 “(ii) such party demonstrates, to an appro-
19 priate medicare administrative contractor under sub-
20 paragraph (D) or the Secretary under subparagraph
21 (E), that an erroneous decision clearly was made.

22 “(D)(i) Any non-governmental party may request (in
23 such form and manner as the Secretary may require) that
24 the appropriate medicare administrative contractor change
25 a fee schedule amount determined under paragraph

1 (2)(A)(i) to correct an erroneous decision in determining
2 such amount.

3 “(ii) Any request under this subparagraph shall in-
4 clude a statement of the basis for the non-governmental
5 party’s belief that an erroneous decision was made in de-
6 termining such amount, together with supporting evidence
7 and a description of any additional data (other than data
8 already in the possession of the appropriate medicare ad-
9 ministrative contractor) that—

10 “(I) is or may be in the possession of the Sec-
11 retary or another medicare administrative con-
12 tractor; and

13 “(II) is necessary to demonstrate that such an
14 erroneous decision exists.

15 “(iii) If the Secretary or another medicare adminis-
16 trative contractor is identified as possessing or potentially
17 possessing additional data identified by a non-govern-
18 mental party in a request under this subparagraph, the
19 Secretary or such contractor, as the case may be, shall
20 make available to the non-governmental party within 30
21 days after the date of the submission of the request any
22 data in their possession that meet the description of the
23 additional data identified in such request, with appro-
24 priate safeguards to protect confidential and proprietary
25 information.

1 “(iv) If additional data are made available to a non-
2 governmental party under clause (iii), such party may
3 amend its request under this subparagraph to incorporate
4 such data within 30 days after the date such data are
5 made available to such party.

6 “(v) An appropriate medicare administrative con-
7 tractor to which a request is submitted under this sub-
8 paragraph shall make a determination with respect to
9 whether to correct the decision that is identified as erro-
10 neous in the request not later than 60 days after the date
11 of the submission of such request, or if later, the date of
12 the submission of an amended request under clause (iv).
13 Such contractor shall determine that the non-govern-
14 mental party submitting the request—

15 “(I) has demonstrated that an erroneous deci-
16 sion clearly was made, correct such erroneous deci-
17 sion, and increase the fee schedule amount as of the
18 first day of the next calendar quarter to reflect the
19 correction of such erroneous decision; or

20 “(II) has failed to demonstrate that an erro-
21 neous decision clearly was made and decline to
22 change the fee schedule amount,
23 and shall provide to the non-governmental party a written
24 explanation of the basis for such determination.

1 “(vi) An appropriate medicare administrative con-
 2 tractor to which a request is submitted under this sub-
 3 paragraph may not reduce a fee schedule amount pursu-
 4 ant to such request, and may reduce such an amount only
 5 pursuant to section 1842(b)(8).

6 “(E)(i) Any non-governmental party may request (in
 7 such form and manner as the Secretary may require) that
 8 the Secretary—

9 “(I) reverse a determination of a medicare ad-
 10 ministrative contractor under subparagraph (D) that
 11 is adverse to the non-governmental party requesting
 12 it;

13 “(II) correct an erroneous decision in the deter-
 14 mination of a limitation amount under paragraph
 15 (4)(B); or

16 “(III) reverse a determination referred to in
 17 subclause (I) and correct an erroneous decision re-
 18 ferred to in subclause (II).

19 “(ii) Any request under this subparagraph shall in-
 20 clude a statement of the basis for the non-governmental
 21 party’s belief that an erroneous decision was made in de-
 22 termining such amount, together with supporting evidence
 23 and a description of any additional data (other than data
 24 already in the possession of the Secretary or the appro-

1 priate medicare administrative contractor reviewing the
2 request under subparagraph (D)) that—

3 “(I) are or may be in the possession of the Sec-
4 retary or another medicare administrative con-
5 tractor; and

6 “(II) are necessary to demonstrate that such an
7 erroneous decision exists.

8 “(iii) If the Secretary or another medicare adminis-
9 trative contractor is identified as possessing or potentially
10 possessing additional data identified by a non-govern-
11 mental party in a request under this subparagraph, the
12 Secretary or such contractor, as the case may be, shall
13 make available to the non-governmental party within 30
14 days after the date of the submission of the request any
15 data in their possession that meet the description of the
16 additional data identified in such request, with appro-
17 priate safeguards to protect confidential and proprietary
18 information.

19 “(iv) If additional data are made available to a non-
20 governmental party under clause (iii), such party may
21 amend its request under this subparagraph to incorporate
22 such data within 30 days after the date such data are
23 made available to such party.

24 “(v) The Secretary shall make a determination of
25 whether to correct the erroneous decision that is the sub-

ject of a request submitted under this subparagraph not later than 60 days after the date of the submission of such request, or if later, the submission of an amended request under clause (iv). The Secretary shall determine that the non-governmental party submitting the request—

“(I) has demonstrated that an erroneous decision clearly was made, correct such erroneous decision, and increase the fee schedule amount as of the first day of the next calendar quarter to reflect the correction of such erroneous decision; or

“(II) has failed to demonstrate that an erroneous decision clearly was made and decline to change the fee schedule amount or national limitation amount, as the case may be,

and shall provide to the non-governmental party with a written explanation of the basis for such determination.

“(vi) The Secretary may not reduce a fee schedule amount pursuant to a request under this subparagraph and may reduce such an amount only pursuant to section 1842(b)(8).

“(F)(i) There shall be no administrative or judicial review under section 1869, 1878, or otherwise of any determination made under subparagraph (D) or (E).

“(ii) Nothing in this paragraph shall be construed as precluding administrative or judicial review of determina-

1 tions of the amount of benefits that are available to a
 2 Medicare beneficiary in a particular case.”.

3 (b) **EFFECTIVE DATE.**—The amendment made by
 4 subsection (a) shall take effect on the date of the enact-
 5 ment of this Act and shall apply to requests for corrections
 6 submitted on or after such date, without regard to whether
 7 final regulations to carry out such amendment have been
 8 issued.

9 **SEC. 202. ISSUANCE OF REGULATIONS ON GAP-FILLING**
 10 **FOR MEDICARE FEE SCHEDULE FOR CLIN-**
 11 **ICAL DIAGNOSTIC LABORATORY TESTS.**

12 Not later than one year after the date of the enact-
 13 ment of this Act, the Secretary of Health and Human
 14 Services shall issue final regulations specifying how an ap-
 15 propriate medicare administrative contractor (as defined
 16 in section 1874A(a)(3)(B) of the Social Security Act (42
 17 U.S.C. 1395kk–1(a)(3)(B)) shall apply a gap-filling meth-
 18 odology in determining fee schedule amounts established
 19 under section 1833(h)(2)(A)(i) of such Act (42 U.S.C.
 20 1395l(h)(2)(A)(i)). Such regulations shall specify—

21 (1) a process for ensuring that the resulting fee
 22 schedule amounts are fair, including a description of
 23 the types of data to be collected for use in such
 24 methodology and the minimum requirements such

1 data shall meet in order to ensure that the data are
2 valid, meaningful, and unbiased;

3 (2) the principles to be employed to ensure that
4 such data are statistically significant and alter-
5 natives to follow if statistically significant data are
6 unavailable;

7 (3) the principles to be followed in using data
8 to calculate fee schedule amounts, including prin-
9 ciples for excluding data that do not meet the re-
10 quirements of paragraph (1) and (2);

11 (4) the methods the Secretary will use to over-
12 see the application of a gap filling methodology by
13 such contractors and the remedies that will be avail-
14 able in cases in which such a contractor fails to com-
15 ply with regulatory requirements; and

16 (5) a process that provides opportunities for the
17 public to participate in the development of fee sched-
18 ule amounts through the application of gap-filling
19 methodologies, including release to the public of data
20 collection protocols and the data derived from such
21 protocols with an opportunity for public comment
22 thereon.

1 **SEC. 203. INCREASED TRANSPARENCY OF PROCESS FOR**
 2 **DETERMINING FEE SCHEDULE AMOUNTS**
 3 **FOR NEW TESTS.**

4 Section 1833(h)(8) of the Social Security Act (42
 5 U.S.C. 1395l(h)(8) is amended—

6 (1) in subparagraph (B)(iii), by inserting “to be
 7 conducted in an inter-active format,” after “meet-
 8 ing,”;

9 (2) in subparagraph (B)(iv)—

10 (A) by inserting “(I)” after “meeting,”;

11 (B) by striking “determination,” and in-
 12 serting “determination and”; and

13 (C) by striking “a request for” and insert-
 14 ing “(II) publishes in the Federal Register a
 15 notice of a period of not less than 60 days dur-
 16 ing which the Secretary will receive”; and

17 (3) in subparagraph (C), by striking “Under
 18 the procedures” and inserting “In the regulations”.

19 **SEC. 204. ADVANCE NOTICE OF CLINICAL DIAGNOSTIC LAB-**
 20 **ORATORY TEST AMOUNTS BEING CONSID-**
 21 **ERED FOR ADJUSTMENT UNDER INHERENT**
 22 **REASONABLENESS AUTHORITY.**

23 (a) **LIMIT ON INHERENT REASONABLENESS AU-**
 24 **THORITY.**—Section 1842(b)(9)(A) of the Social Security
 25 Act (42 U.S.C. 1395u(b)(9)(A)) is amended by adding at
 26 the end the following: “Before publishing a proposed no-

1 tice under subparagraph (B) with respect to any clinical
 2 diagnostic laboratory test being considered for adjustment
 3 under paragraph (8), advance notice that such test is
 4 being considered for such an adjustment shall be provided
 5 to non-governmental parties (as defined in section
 6 1833(h)(9)(A)(iv)) at the meeting required by section
 7 1833(h)(8)(B)(iii), together with an opportunity for such
 8 representatives and other individuals to make oral com-
 9 ments on the appropriateness of such an adjustment for
 10 such test.”.

11 (b) CONFORMING CHANGE.—Section 1833(h)(8)(B)
 12 of such Act (42 U.S.C. 1395l(h)(8)(B)) is amended by
 13 adding at the end the following:

14 “At the meeting required by clause (iii), the Secretary
 15 shall provide advance notice of inherent reasonableness ad-
 16 justments under section 1842(b)(8) that are being consid-
 17 ered for clinical diagnostic laboratory tests, and afford an
 18 opportunity for non-governmental parties (as defined
 19 1833(h)(9)(A)(iv)) at the meeting to comment orally on
 20 the appropriateness of such an adjustment.”.

21 (c) EFFECTIVE DATE.—The amendments made by
 22 this section shall become effective on January 1, 2008,
 23 and shall apply to inherent reasonableness adjustments
 24 that have not been proposed as of such date.

○